

Appl. No.: 09/857,078
Group Art Unit: 1616
Response to Paper No. 11

REMARKS

Claims 10-30 are currently pending in the instant application.

Claims 10-20 stand allowed and claims 27 and 28, while objected to as being dependent upon a rejected base claim, would be allowable if rewritten in independent form.

Claims 21 and 22 have been amended to specify that the claimed subject matter encompasses a reaction product *consisting essentially of* a sterol phosphate prepared in accordance with the processes of claims 10 and 20, respectively. Claim 23 has been amended to specify that the cosmetic composition claimed therein comprises a sterol phosphate *incorporated in a formulation base*. The amendments to claims 21-23 are supported by the claims as originally filed and in the Specification, for example, at page 3, line 28, through page 4, line 10; and in the Examples. No new matter has been introduced. The amendments to claims 21-23 are proper after final rejection as they place the application in a condition for allowance, as explained in more detail below. A complete listing of all claims ever presented is included herein in accordance with 37 C.F.R. §1.121(c). Entry of the amendments to claims 21-23 is therefore proper and respectfully requested.

In Paper No. 11, the Examiner maintains the rejections of claims 21 and 22 under 35 U.S.C. §102(b), as being anticipated by Cremlyn or Ramirez, and makes the rejection final, essentially for the reasons of record set forth in the Office Action dated May 9, 2003 (Paper No. 8). The Examiner notes that Applicants' arguments in response to Paper No. 8 regarding the lack of certain impurities in the claimed products were considered, but not found persuasive because the claims did not exclude such impurities. (See, Paper No. 11, p. 2).

Applicants respectfully traverse the Examiner's rejection, along with the contentions and arguments in support thereof for the following reasons.

Applicants' claimed invention, *as amended*, is directed to reaction products which consist essentially of a sterol phosphate prepared by the processes according to the invention. As explained in response to Paper No. 8 and as reiterated below, the processes according to the invention produce sterol phosphates which lack certain prior art impurities or by-products. The amended claim language clearly excludes the presence of the impurities.

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Applicants respectfully submit that the claimed product, *as amended*, lacks the prior art impurities or by-products and is in fact different than the prior art products. To be clear, these differences are not solely in the processes used to make each product. The differences in the processes used to make the products result in differences in the end products themselves.

As discussed in response to Paper No. 8, Cremlyn discloses the production of various sterol compounds, including certain sterol dihydrogen phosphates, via the *hydrolysis* of the corresponding sterol phosphoro-dichloridates. (See, Cremlyn, p. 2305, 2nd col., lines 14-24). Cremlyn specifically discloses the simultaneous production of the corresponding sterol chloride as a result of such hydrolysis, and suggests a mechanism for their formation. (See, *id.*, at lines 27-31). Specifically, Cremlyn states that, "[t]he cholesteryl chloride *formed in these hydrolyses* probably arises, in the main, from intermolecular S_N2 attack by the evolved hydrogen chloride . . ." (See, *id.* (*emphasis added*)). Thus, the products disclosed by Cremlyn contain sterol chloride compounds. The claimed product, as amended, excludes sterol chloride compounds as disclosed in Cremlyn.

Applicants' claimed sterol phosphates are the products of processes which do not employ phosphorodichloridates, and accordingly, do not contain sterol chlorides resulting from their preparation. In other words, Applicants' claimed compounds are different than the products disclosed by Cremlyn. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) over Cremlyn.

Also, as discussed in response to Paper No. 8, Ramirez discloses a process for preparing sterol phosphates wherein a source of metaphosphate is reacted with a sterol. Ramirez discloses the use of (1-phenyl-1,2-dibromoethyl)phosphonic acid only, because of its ready availability and its convenient rate of decomposition in aprotic solvents such as dichloromethane. (See, Ramirez, p. 1418, "Results and Discussion"). Ramirez discloses a specific synthetic route for the preparation of steroid dihydrogen phosphates wherein (1-phenyl-1,2-dibromoethyl)phosphonic acid is reacted with the dried steroid in a solution of anhydrous dichloromethane. In the disclosed synthetic procedure, Ramirez specifically points out the presence of unwanted α -bromostyrene by-product in the phosphate product. (See, *id.*, at pp.

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1419-20). The claimed product, as amended, excludes α -bromostyrene by-products as disclosed in Ramirez.

Applicants' claimed sterol phosphates are the products of processes which do not employ (1-phenyl-1,2-dibromoethyl)phosphonic acid, and accordingly, do not contain brominated by-products resulting from their preparation. Again, Applicants submit that the process, as set forth in the amended claims, *results* in a different product than that which is disclosed in the prior art as containing the brominated by-products. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) over Ramirez.

Also, in Paper No. 11, the Examiner maintains the rejection of claims 23-26, 29 and 30 under 35 U.S.C. §103(a), as being unpatentable over U.S. Pat. No. 5,958,433 of Simonnet (hereinafter referred to as "Simonnet"), in view of U.S. Pat. No. 6,051,250 of Ribier, *et al.* (hereinafter referred to as "Ribier"), and makes the rejection final essentially for the reasons of record set forth in Paper No. 8.

Applicants respectfully traverse the Examiner's rejection, and the arguments and contentions in support thereof, for the following reasons.

Claims 23 through 28, as amended, are directed to cosmetic preparations which comprise a sterol phosphate of the general formula (I) incorporated into a formulation base. Claims 29 and 30 are directed to a method of deodorizing the human body by applying an effective amount of such a cosmetic composition; and a method of enhancing the deodorizing effects of a cosmetic preparation by combining an effective amount of a sterol phosphate of the general formula (I) with a cosmetic preparation containing at least one deodorizing agent; respectively.

The cited references fail to teach or suggest the claimed cosmetic composition, as amended, and fail to satisfy the requirements for establishing *prima facie* obviousness.

Simonnet discloses a dispersion containing vesicles which comprise a lamellar phase made from at least one silicone surfactant. (*See*, Simonnet, claim 1). An ionic

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amphiphilic lipid may be incorporated into the lamellar phase to prevent flocculation of the vesicles. (See, Simonnet, claim 11). Among the ionic amphiphilic lipids which can be incorporated into the lamellar phase are alkali metal salts of dicetyl- and dimyristylphosphate; alkali metal salts of cholesterol sulphate; alkali metal salts of cholesterol phosphate; lipoamino acids such as mono- and disodium acylglutamates; sodium salts of phosphatidic acid; phospholipids; and alkylsulphonic derivatives of the formula disclosed therein in which R represents C₁₆-C₂₂ alkyl, preferably C₁₆H₃₃ or C₁₈H₃₇, or a mixture thereof, and M is an alkali metal such as sodium and potassium; and mixtures thereof. (See, Simonnet, col. 3, lines 33-52).

The lamellar phase of the vesicles disclosed in Simonnet represents a lipid bilayer into which such an amphiphilic lipid may be incorporated. *Simonnet does not teach or suggest the addition of a sterol phosphate to an already formed cosmetic formulation base.* The dispersion disclosed by Simonnet contains these vesicles which are essentially spherical lipid bilayers encapsulating an internal phase. Within the lipid bilayer, an amphiphilic lipid may be incorporated. *The amphiphilic lipid is not combined with a formulation base as claimed.*

According to the teachings of Simonnet, the only reason one of ordinary skill in the art would be motivated to incorporate an amphiphilic lipid into a composition would be if that composition contained lamellar based lipid vesicles which could be stabilized by the incorporation of such an additional lipid. Moreover, Simonnet provides no motivation towards the selection of cholesterol phosphates over any other amphiphilic lipids. Accordingly, one of ordinary skill in the art would find no motivation to combine an already prepared cosmetic formulation base and a sterol phosphate to produce a cosmetic preparation as claimed.

Ribier fails to remedy the deficiencies of Simonnet. In much the same manner, Ribier is directed to vesicles formed by lamellar lipid bilayers, into which stabilizing agents may be incorporated. This does not provide one of ordinary skill in the art with either a teaching or suggestion, nor any motivation, to prepare a cosmetic composition by combining a formulation base and a sterol phosphate.

None of the cited references teaches or suggests the combination of a formulation base and a sterol phosphate. Moreover, there is no teaching or suggestion in any of the cited

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references which would motivate one of ordinary skill in the art to modify the teachings of the references to include an amphiphilic lipid outside of a lamellar lipid bilayer comprising a silicone surfactant. Absent any teaching or suggestion of each and every element, and given that there is no motivation to modify the references to arrive at the claimed invention, it cannot reasonably be argued that one of ordinary skill in the art would expect to successfully achieve the claimed invention.

With respect to the methods of claims 29 and 30, Applicants respectfully submit that the cited references *further* fail to teach or suggest the application of an odor-suppressing effective amount of the cosmetic preparation to an area of the body to be deodorized.

Thus, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness based on the cited references, as none of the three criteria necessary to establish such a *prima facie* case of obviousness has been satisfied. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of the claims under 35 U.S.C. §103(a).

In view of the amendments made herein and the remarks set forth above, Applicants submit that the currently rejected claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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